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Impact of the 2016 ASE/EACVI recommendations on the prevalence of diastolic dysfunction in the general population

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Aims Diastolic dysfunction (DD) is frequent in the general population; however, the assessment of diastolic function remains challenging. We aimed to evaluate the impact of the recent 2016 American Society of Echocardiography (ASE)/European Association of Cardiovascular Imaging (EACVI) recommendations in the prevalence and grades of DD compared with the 2009 guidelines and the Canberra Study Criteria (CSC).

Methods and results Within a population-based cohort, a total of 1000 individuals, aged ≥45 years, were evaluated retrospectively. Patients with previously known cardiac disease or ejection fraction <50% were excluded. Diastolic function was assessed by transthoracic echocardiography. DD prevalence and grades were determined according to the three classifications. The mean age was 62.0 ± 10.5 years and 37% were men. The prevalence of DD was 1.4% ($n = 14$) with the 2016 recommendations, 38.1% ($n = 381$) with the 2009 recommendations, and 30.4% ($n = 304$) using the CSC. The concordance between the updated recommendations and the other two was poor (from $k = 0.13$ to $k = 0.18$, $P < 0.001$). Regarding the categorization in DD grades, none of the 14 individuals with DD by the 2016 guidelines were assigned to Grade 1 DD, 64% were classified as Grade 2, 7% had Grade 3, and 29% had indeterminate grade.

Conclusion The application of the new 2016 ASE/EACVI recommendations resulted in a much lower prevalence of DD. The concordance between the classifications was poor. The updated algorithm seems to be able to diagnose only the most advanced cases.

Keywords diastole • echocardiography • diastolic dysfunction • heart failure

Introduction

Left ventricular (LV) diastolic dysfunction (DD) is frequent in the general population[1] and contributes to the development and progression to heart failure with preserved ejection fraction (HFpEF).[2,3] DD is an important predictor of incident heart failure[4] and total mortality.[5] However, the assessment of diastolic function remains challenging, because several parameters and different criteria have been used for its evaluation. The majority of available cut-off values and recommendations for diagnosing and grading DD were derived from experienced international centres,[1,6,7] and the heterogeneity and ambiguity of the different definitions led to a significant variability

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in the reported prevalence and grading of DD.[8] Recently, the 2016 American Society of Echocardiography (ASE)/European Association of Cardiovascular Imaging (EACVI) recommendations have been published.[9] Acknowledging the complexity of the 2009 ASE/European Association of Echocardiography (EAE) recommendations,[7] this update aimed to simplify the diagnosis and classification of DD in daily clinical practice, using the most feasible and reproducible parameters of diastolic function and providing algorithms with hierarchical organization. Our aim was to evaluate the impact of the 2016 ASE/EACVI recommendations in the prevalence and grades of DD in the general population, comparing with the 2009 guidelines and the Canberra Study Criteria (CSC).

Methods

Study population

The study population included participants from the EPIPorto cohort study, which at baseline was representative of the adult population of Porto (Portugal). Between 1999 and 2003, the EPIPorto population was selected using random digit dialling, with households as sampling frame. In each household, a random selection of one person aged 18 years or more was made and refusals were not substituted within the same household. A total of 2485 individuals were recruited (proportion of participation 70%).[10] From October 2006 to July 2008, participants aged 45 years or more were evaluated with a cardiovascular clinical history, physical examination, detailed anthropometric parameters, fasting blood samples and submitted to a comprehensive transthoracic echocardiography (TTE). From the initial 2048 participants, 134 (6.5%) had died, 198 (9.7%) refused to be re-evaluated, and 580 (28.3%) were lost to follow-up. For this retrospective analysis, we excluded individuals with systolic dysfunction (ejection fraction <50%), previous myocardial infarction, percutaneous or surgical myocardial revascularization, more than mild valvular heart disease, sinus tachycardia, atrial fibrillation or flutter, permanent pacemaker, and complete left bundle branch block (136 excluded). Written informed consent was obtained from all participants, and the local ethics committee (‘Comissão de Ética do Centro Hospitalar S. João, EPE’) approved the study. The investigation conforms to the principles of the 1975 Declaration of Helsinki.

Clinical variables definitions

Arterial hypertension was determined as a systolic blood pressure ≥140mmHg, a diastolic blood pressure ≥90mmHg, or the use of antihypertensive drugs. Obesity was defined as body mass index ≥30 kg/m^2. Type 2 diabetes mellitus was determined by self-reported diagnosis, fasting glucose level of at least 126 mg/dL, or the use of antidiabetic agents. Dyslipidaemia was defined as total serum cholesterol ≥220 mg/dL or the use of lipid-lowering drugs. Metabolic syndrome was defined according the American Heart Association updated National Cholesterol Education Program Adult Treatment Panel III criteria. Symptomatic heart failure was determined according to the definition by the American College of Cardiology and American Heart Association.[11] Exertional dyspnoea, orthopnoea, nocturnal paroxysmal dyspnoea, evening lower limb oedema (in the absence of chronic venous insufficiency), jugular venous distension, and rales were considered symptomatic heart failure when at least two of them were present.

Echocardiographic evaluation

TTE studies were performed using the same ultrasound system (Hewlett-Packard Sonos 5500). Stored images were analysed offline by two experienced cardiologists, blinded to clinical data. Chamber quantification and function was assessed according the 2005 ASE/EAE recommendations.[12] Left atrial (LA) volume was measured at end-ventricular systole, avoiding foreshortening of the atrium, using apical views and Simpson’s rule. Volumes were indexed to body surface area. LV systolic function was evaluated by determination of ejection fraction using the modified Simpson’s rule from biplane using four and two-chamber views. Types of LV hypertrophy were determined using LV mass index and relative wall thickness, according to the most recent recommendations.[13] Evaluation of diastolic function was performed from TTE apical views, using recorded velocities at end expiration, averaging over three consecutive cardiac cycles. Mitral inflow velocities (E-wave and A-wave) and deceleration time (DT) were measured at the tips of the mitral leaflets with pulsed-wave Doppler. Lateral mitral annulus velocities (e' and a') were measured with tissue Doppler imaging. The E/A ratio and the lateral E/e' ratio were calculated accordingly. Tricuspid regurgitation (TR) peak velocity was determined using continuous-wave Doppler and simplified Bernoulli equation.

Classification of diastolic function

DD prevalence and grades were determined using three different classifications. The first classification was based on the 2009 ASE/EAE recommendations for the evaluation of LV diastolic function.[7] This grading system suggests starting with e' velocities and indexed LA volume. After that, we used E/A ratio, DT and lateral E/e' cut-offs from the five suggested measures. At least two positive measures were needed to attribute a DD grade. When it was not possible to grade DD due to discrepancies between different parameters, they were considered as indeterminate. The second grading system was based on the CSC.[6] This classification categorizes individuals based on mitral inflow (E/A and DT), pulmonary venous inflow, and lateral E/e' ratio. In case of doubt or missing value, patients were classified as indeterminate. Finally, the third classification used the 2016 ASE/EACVI recommendations for the evaluation of diastolic function.[9] The first step relies on the diagnosis of DD in patients with normal LV ejection fraction. Using E/e' ratio, lateral e' velocity, TR velocity, and indexed LA volume, the patients were classified as having normal diastolic function, DD, or indeterminate. These guidelines recommend using the average E/e' ratio, but it is recognized that some laboratories, similar to ours, only measure lateral or septal e'. Therefore, we used the recommended cut-off for lateral E/e' ratio (>13). The second step consisted in applying the 2016 DD grading algorithm to individuals previously classified as having DD in Step 1. The grading system starts with the evaluation of E/A ratio and E-wave velocity, and then, using lateral E/e', TR, and indexed LA volume, the patients were graded. DD classification was performed by two independent investigators blinded to patient characteristics.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD), and categorical variables are presented as absolute numbers and percentages. Comparisons between normal, DD, and indeterminate individuals were performed using one-way analysis of variance or Kruskal–Wallis test for continuous variables and the χ^2 test or exact Fisher’s test for categorical variables, as appropriate. The concordance between the three classifications was determined using kappa coefficients and proportion of agreement. The concordance was defined as poor (0–0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), and optimal (0.81–1).[14] The reclassification percentage was determined as: 100 - proportion of agreement. A P-value of <0.05 was considered for statistical significance. All tests were two tailed. Data analysis was performed using SPSS version 23 (SPSS Inc., Chicago, IL, USA).

Table 1 Clinical and echocardiographic characteristics of the study sample

	All patients (n = 1000)
Age (years)	62.0 ± 10.5
Gender (male)	370 (37)
Body mass index (kg/m^2)	27.5 ± 4.6
Arterial hypertension	702 (70.4)
Obesity	253 (25.3)
Dyslipidaemia	548 (54.8)
Type 2 diabetes mellitus	114 (11.4)
Metabolic syndrome	406 (41.2)
Heart failure	46 (4.6)
NYHA Class I/II (%)	30/50
NYHA Class III (%)	20
Medication	
Inhibitors of the renin–angiotensin system	232 (23.2)
Calcium channel blocker	70 (7)
Diuretics	111 (11.1)
Ejection fraction (%)	60.7 ± 6.0
Left atrial volume index (mL/m^2)	28.8 ± 9.9
Left ventricular end-systolic volume index (mL/m^2)	26.7 ± 8.9
Left ventricular end-diastolic volume index (mL/m^2)	66.0 ± 16.0
Left ventricular mass index (g/m^2)	79.3 ± 19.0
Eccentric left ventricular hypertrophy	72 (7.2)
Concentric left ventricular hypertrophy	24 (2.4)
Left ventricular concentric remodelling	39 (3.9)
Tricuspid regurgitation peak velocity (cm/s)	2.3 ± 0.3
E/A ratio	0.97 ± 0.32
Deceleration time (ms)	237 ± 54
Isovolumetric relaxation time (ms)	91.6 ± 15.8
Lateral e′ velocity (cm/s)	10.5 ± 3.2
Lateral *E/e′*	7.4 ± 2.7

Data are represented as mean ± standard deviation for continuous variables and n (%) for categorical variables.
NYHA, New York Heart Association.

Results

In this study, 1000 individuals were included, 37% were men, with a mean age of 62 ± 10.5 years, as detailed in *Table 1*. The feasibility of the four echocardiographic parameters recommended by the 2016 guidelines for the diagnosis of DD was very high (98.4–100%). We assessed the prevalence of these diastolic parameters in our population: LA volume index ≥34 ml/m^2 was present in 26%, TR velocity >2.8 m/s in 1.2%, lateral e′ velocity <10 cm/s in 44.6%, and lateral *E/e′* >13 in 4.2%. The prevalence of DD was 1.4% (n = 14) with the 2016 recommendations, 38.1% (n = 381) with the 2009 recommendations, and 30.4% (n = 304) using the CSC, as shown in *Figure 1*. *Table 2* presents the comparison of the patient characteristics between the different groups (normal, DD, and indeterminate) using the 2009 and the 2016 guidelines. With the 2016 recommendations, we observed significant differences in several clinical and echocardiographic parameters between groups. On the contrary, using the 2009 guidelines, we did not observe statistical differences between the groups, regarding gender, obesity, LA and LV volume indexes, and ejection fraction. The concordance between the 2016 and 2009 recommendations was poor (k = 0.18, P < 0.001), with a reclassification rate of 41%, as showed in *Figure 2*. From the 381 patients classified as having DD using the 2009 recommendations, 250 (66%) patients were reclassified as normal patients and 31% (120/381) as indeterminate cases. There was agreement in 11 of the 14 individuals labelled as DD cases with the 2016 recommendations and the previous guidelines, as detailed in *Table 3*. Of the 15% indeterminate cases by the newer recommendations, 79% (120/152) were classified as having DD by the 2009 recommendations. Comparing the 2016 recommendations with the CSC, there was also a poor agreement in the prevalence of DD (k = 0.13, P < 0.001), with a reclassification rate of 41%. The application of the 2016 guidelines resulted in reclassification of 67% (205/304) of DD patients as normal patients and of 70% (71/101) of indeterminate patients as normal individuals, as detailed in *Table 4*. Furthermore, 60% (91/152) of the indeterminate cases by the 2016 recommendations were classified as having DD by the CSC. Finally, between the 2009 recommendations and the CSC, we found a fair

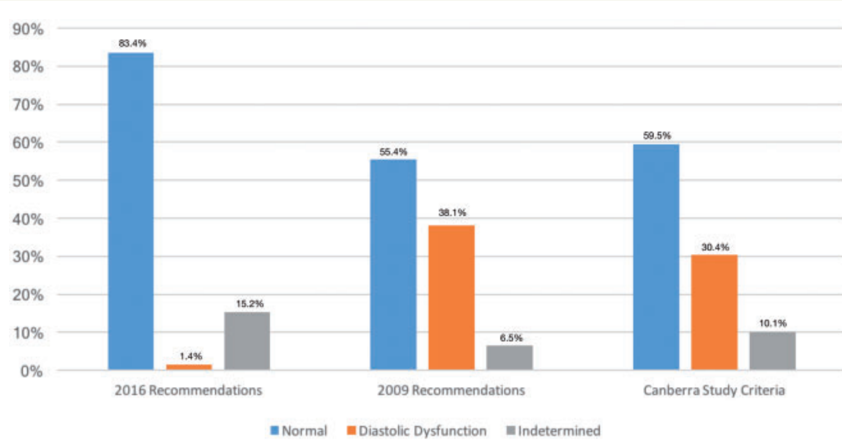

Figure 1 Prevalence of diastolic dysfunction, according to each classification.

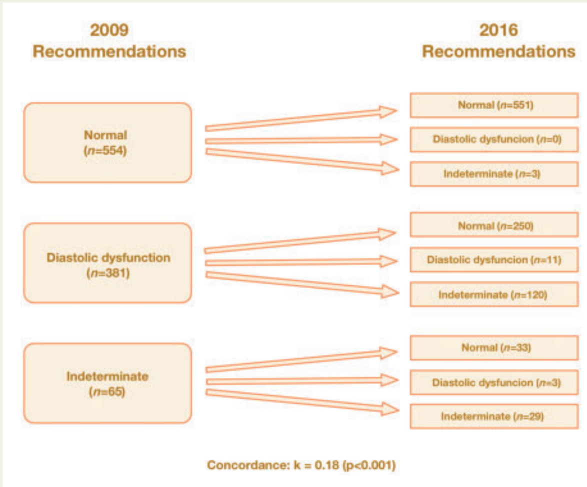

Figure 2 Concordance in diastolic dysfunction prevalence according to the 2009 ASE/EAE recommendations and the 2016 ASE/EACVI recommendations. Number of normal, diastolic dysfunction, and indeterminate cases as classified by the 2009 recommendations are represented on the left. Patients reclassified by the 2016 updated guidelines are reported on the right.

agreement ($k = 0.35$, $P < 0.001$). The categorization in DD grades according to the different algorithms is shown in *Figure 3*. Using the 2016 guidelines, none of the 14 subjects with DD were assigned as Grade 1 DD. Most of the individuals (64%) were classified as Grade 2 DD, 7% as Grade 3 DD, and 29% as indeterminate grade.

Discussion

Prevalence of diastolic dysfunction

In this population, we found that the application of the 2016 diastolic function recommendations resulted in a significantly lower prevalence of DD (1.4%), when compared with the estimation by the 2009 guidelines (38.1%) and the CSC (30.4%). Furthermore, the concordance rates were poor, with reclassification rates exceeding 40%. The use of the 2016 classification also resulted in a significant increase in the number of indeterminate cases (about 15%). We observed that between 60% and 80% of those indeterminate cases were considered to have DD by the previous guidelines and the CSC. Therefore, considering these data and the clinical and echocardiographic characteristics of these individuals, it is plausible that these individuals could also have a milder degree of DD, although not fulfilling yet all the

Table 2 **Comparison of clinical and echocardiographic characteristics between patients with normal diastolic function, diastolic dysfunction, and indeterminate cases, using the 2016 and 2009 recommendations**

	2016 Recommendations				2009 Recommendations			
	Normal ($n = 834$)	DD ($n = 14$)	Indeterminate ($n = 152$)	*P*-value	Normal ($n = 554$)	DD ($n = 381$)	Indeterminate ($n = 65$)	*P*-value
Age (years)	60.4 ± 10.1	72.2 ± 11.6	69.7 ± 8.5	<0.001	57.6 ± 9.4	67.3 ± 9.3	68.1 ± 9.1	<0.001
Male gender	322 (38.6)	6 (42.9)	42 (27.6)	0.031	208 (37.5)	140 (36.7)	22 (33.8)	0.826
Arterial hypertension	550 (66.2)	14 (100)	137 (90.7)	<0.001	325 (58.8)	321 (84.9)	55 (84.6)	<0.001
Dyslipidaemia	444 (53.2)	6 (42.9)	98 (64.5)	0.023	276 (49.8)	234 (61.4)	38 (58.5)	0.002
Type 2 diabetes	81 (9.7)	5 (35.7)	28 (18.4)	<0.001	44 (7.9)	55 (14.4)	15 (23.1)	<0.001
Obesity	198 (23.7)	4 (28.6)	51 (33.6)	0.036	133 (24)	98 (25.7)	22 (33.8)	0.217
Metabolic syndrome	309 (37.7)	7 (50.0)	90 (59.2)	<0.001	168 (30.7)	201 (53.9)	37 (56.9)	<0.001
Body mass index (kg/m^2)	27.3 ± 4.7	28.1 ± 5.0	28.3 ± 4.1	0.032	26.9 ± 4.9	28.1 ± 4.2	28.8 ± 4.0	<0.001
Heart failure	27 (3.2)	2 (14.3)	17 (11.2)	<0.001	16 (2.9)	27 (7.1)	3 (4.6)	0.009
Ejection fraction (%)	60.7 ± 6.2	58.9 ± 6.9	59.1 ± 5.3	0.008	60.8 ± 5.9	60.2 ± 6.5	59.0 ± 5.6	0.060
LA volume index (mL/m^2)	26.8 ± 8.4	44.1 ± 10.9	38.2 ± 10.5	<0.001	28.3 ± 9.3	29.6 ± 10.6	28.0 ± 10.3	0.139
LVESV (mL/m^2)	25.9 ± 8.6	32.7 ± 11.7	30.3 ± 9.0	<0.001	26.4 ± 8.7	27.0 ± 9.2	27.6 ± 8.8	0.445
LVEDV (mL/m^2)	64.8 ± 15.5	77.1 ± 18.1	71.7 ± 17.0	<0.001	65.9 ± 15.7	66.4 ± 16.8	64.7 ± 14.5	0.696
LV mass index (g/m^2)	77.0 ± 17.2	107.0 ± 34.0	89.3 ± 21.0	<0.001	74.1 ± 16.2	86.0 ± 20.7	84.9 ± 16.6	<0.001
LV hypertrophy	57 (6.9)	4 (28.6)	35 (23.2)	<0.001	20 (3.6)	67 (17.7)	9 (13.8)	<0.001
LV concentric remodelling	33 (4)	1 (7.1)	5 (3.3)	0.517	16 (2.9)	19 (5)	4 (6.2)	0.130
TR peak velocity (cm/s)	2.3 ± 0.3	2.7 ± 0.2	2.4 ± 0.3	<0.001	2.3 ± 0.3	2.4 ± 0.2	2.4 ± 0.3	0.006
E/A ratio	1.0 ± 0.3	1.1 ± 0.6	0.8 ± 0.4	<0.001	1.1 ± 0.3	0.8 ± 0.3	0.9 ± 0.2	<0.001
DT (ms)	231.7 ± 49.9	233.9 ± 54.1	267.7 ± 63.0	<0.001	222.5 ± 45.1	258.2 ± 58.0	239 ± 52.8	<0.001
IVRT (ms)	90.4 ± 15.4	94.4 ± 24.2	98.0 ± 15.6	<0.001	89.2 ± 14.8	95.8 ± 16.1	87.5 ± 18.1	<0.001
Lateral e' velocity (cm/s)	11.1 ± 3.1	7.1 ± 1.7	7.5 ± 1.7	<0.001	12.8 ± 2.4	7.8 ± 1.4	7.3 ± 1.5	<0.001
Lateral E/e'	6.8 ± 2.0	13.0 ± 4.3	10.0 ± 3.5	<0.001	6.0 ± 1.5	8.7 ± 2.5	11.5 ± 3.6	<0.001

Data are represented as mean ± standard deviation for continuous variables and *n* (%) for categorical variables.
LVESV, left ventricular end-systolic volume; LVEDV, left ventricular end-diastolic volume; IVRT, isovolumetric relaxation time.

Table 3 **Reclassification table of diastolic dysfunction prevalence using the 2009 and 2016 recommendations**

		2009 Recommendations			
		Normal	**DD**	**Indeterminate**	**Total**
2016 Recommendations	Normal	551	250	33	834
	DD	0	11	3	14
	Indeterminate	3	120	29	152
	Total	554	381	65	1000

Table 4 **Reclassification table of diastolic dysfunction prevalence for the 2016 recommendations and Canberra study criteria**

		Canberra study criteria			
		Normal	**DD**	**Indeterminate**	**Total**
2016 Recommendations	Normal	558	205	71	834
	DD	2	8	4	14
	Indeterminate	35	91	26	152
	Total	595	304	101	1000

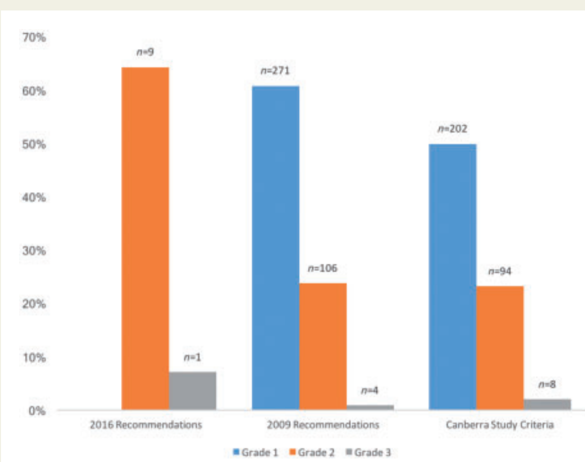

Figure 3 Diastolic dysfunction grades, according to each classification.

echocardiographic criteria recommended in the 2016 guidelines. Other community-based studies reported prevalence of DD ranging from 11.1% to 36%, although applying different definitions and diagnostic algorithms.[1,6,15–17] The large difference in the prevalence of DD between the 2016 recommendations and the other two classifications is striking and unexpected. A similar difference was also found by Huttin *et al.*[18] in a population-based study with 1485 individuals. The authors reported a DD prevalence of only 1.3%, much lower than the prevalence obtained when using previous algorithms. One possible explanation for this difference might be related with the inclusion of the TR peak velocity in the newer recommendations. Pulmonary systolic hypertension has been used as a surrogate measure of clinically significant pulmonary venous hypertension in patients with HFpEF,[19] being associated with echocardiographic evidence of advanced DD due to chronic pressure overload.[20] Therefore, TR velocity is a parameter that probably reflects more advanced and severe DD. In our sample, we observed a TR velocity >2.8 m/s in only 1.2%. Therefore, the observations of a significantly lower prevalence of DD, associated with the amount of indeterminate cases by the 2016 guidelines that were considered DD cases by the other two recommendations (60–80%) suggest that the newer algorithm and the inclusion of the TR parameter might have resulted in lower sensitivity and higher specificity to diagnose DD. Consistent with these observations, Obokata *et al.*[21] showed that the new algorithm was specific but poorly sensitive, being able to identify only 34% of individuals with invasively proven HFpEF. Recently, the Euro-Filling study[22] reported a fair sensitivity to diagnose elevated LV filling pressures with the 2016 recommendations in patients undergoing simultaneous invasive LV end-diastolic pressure measurement. Additionally, they concluded that the algorithm was suboptimal in patients with preserved ejection fraction. Also using an echocardiographic–catheterization design, Andersen *et al.*[23] validated the 2016 algorithm in a population of 450 patients, revealing good accuracy for the diagnosis of elevated filling pressures. However, the studied population was very different from ours, since patients without cardiac diseases were excluded and only the algorithm for known cardiac disease was used.

Categorization in diastolic dysfunction grades

Regarding the categorization in DD grades, the majority of patients with DD were classified as Grade II of DD (9/14) when applying the

2016 grading algorithm, with only one as Grade III DD, and none was classified as Grade I DD. Another important observation using the new classification is the large proportion of indeterminate grade cases (29%). According to the 2016 DD grading algorithm, we can imply that the indeterminate individuals correspond to cases in which only two of three measures could be assessed (*E*/*e*′, TR velocity, and LA volume index) and those two measures were discordant. It is known that the concordance of the various echocardiographic diastolic measures is lower in patients with preserved ejection fraction,[24] such as our cohort. The 2016 recommendations do not provide further guidance in cases of discordant measures to use additional parameters, except for the pulmonary vein *S*/*D* ratio in patients with LV systolic dysfunction. The prevalence and grades of DD have prognostic impact,[25] with a progressive increased risk of mortality with the progression of DD,[26] even in patients with preserved LV ejection fraction.[27] Thus, the observed differences between the algorithms might have important clinical relevance. The rationale of the 2016 algorithm was the need to overcome the ambiguities associated of the 2009 guidelines, which provided many parameters without suggesting a minimal number of measures or a hierarchical classification, resulting in suboptimal agreement between observers.[8] However, the updated recommendations possibly caused an oversimplification of the grading process, at least in patients with preserved ejection fraction, leading to discordant measures and possibly lower discriminatory capacity to detect and grade DD. The absence of patients classified as Grade I DD is another concern, suggesting again that the new algorithm might be able to detect only the most advanced cases. Future prospective studies will need to evaluate whether the differences in DD prevalence and grades with the 2016 recommendations will change the role of DD as a prognosis marker.

Limitations

There was no specific gold standard to diagnose DD, thus the diagnostic accuracy of the three different classifications could not be established. We included only patients with preserved LV ejection fraction; therefore, these observations cannot be extrapolated to patients with reduced ejection fraction. We did not assess pulmonary venous inflow pattern, a parameter that is included in the CSC and 2009 algorithms, but we do not expect this would significantly change the reported results. *E*′ velocity was assessed only at the lateral side of the mitral annuls, and cases of discordant medial and lateral *e*′ velocities could have been misdiagnosed. Also, since our population had a high prevalence of arterial hypertension and because DD develops earlier and greatly at the septal wall in hypertensive cardiomyopathy,[28] the assessment of *E*′ only at the lateral side might have contributed to underestimation of DD true prevalence. Nevertheless, the relative differences between algorithms is probably not explained by this, since we used the provided cut-offs for the use of lateral *E*′ velocity by the CSC and 2009 criteria.

Conclusions

The application of the new 2016 ASE/EACVI recommendations for diastolic function assessment resulted in a much lower prevalence of DD. The concordance between the different diagnostic algorithms was poor, which significantly changed the prevalence and categorization in DD grades. The updated classification might be able to detect only the most advanced cases. The prognostic impact of this criteria needs to be further investigated in future prospective studies.

Conflict of interest: None declared.

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